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Management of Low Density Lipoprotein Cholesterol at a Primary Care Diabetes Clinic in Kuwait

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Abstract

Aims:

To evaluate the impact of clinical audit and focused interventions on reducing cardiovascular diseases risk by treating Low Density Lipoprotein Cholesterol (LDL-C) in patients with type 2 diabetes attending a primary care clinic in Kuwait.

Methods:

Using LDL as a surrogate for cardiovascular risk, the audit team performed a clinical audit with focus on the care process indicator of statin prescription. The basic audit reviewed 100 patients' medical records retrospectively to assess patients' lipid profiles and statin prescription. A lipid management protocol and algorithm based on national clinical practice guidelines distributed to all healthcare professionals and was implemented for 3 months followed by re-audit of another 100 records. Descriptive and comparative statistics (pre and post) were performed using SPSS, version 22.

Results:

Statin prescription increased significantly from (26%) in the basic audit to (85%) in the post-intervention audit ($p<0.001$). The mean LDL-C value decreased significantly from $3.37\pm0.67\text{mmol/L}$ to $2.71\pm0.79\text{mmol/L}$, $p<0.001$. Mean total cholesterol was significantly reduced from $5.15\pm0.73\text{mmol/L}$ to $4.68\pm0.88\text{mmol/L}$, $p<0.001$. Ten years CHD risk decreased from $18.46\pm11.1\%$ to $16.8\pm12.23\%$, $p=0.152$.

Conclusions:

Implementing a clinical audit coupled with focused intervention was successful in improving management of LDL-C among patients with type 2 diabetes mellitus attending the primary healthcare sector in Kuwait.

Keywords: diabetes; low density lipoprotein cholesterol; audit; clinical guidelines, Kuwait.

Introduction:

The prevalence of diabetes mellitus is high in North Africa and the Middle East region (9.1%) with estimated 342,000 annual deaths due to diabetes.{ ADDIN EN.CITE <EndNote><Cite><Author>Federation</Author><Year>2013</Year><RecNum>1</RecNum><DisplayText>[1]</DisplayText><record><rec-number>1</rec-number><foreign-keys><key app="EN" db-id="erv2s2vsnwtr24eswtrpv5xs5dsx29vpsxsp" timestamp="1527905021">1</key></foreign-keys><ref-type name="Web Page">12</ref-type><contributors><authors><author>International Diabetes Federation </author></authors></contributors><titles><title>International Diabetes Federation Atlas </title></titles><dates><year>2013</year></dates><urls><related-urls><url>www.idf.org/diabetesatlas.</url></related-urls></urls></record></Cite></EndNote>}

According to the International Diabetes Federation, Kuwait is among the top ten countries affected by diabetes with estimated prevalence of 23.09%.{ ADDIN EN.CITE <EndNote><Cite><Author>Federation</Author><Year>2013</Year><RecNum>1</RecNum><DisplayText>[1]</DisplayText><record><rec-number>1</rec-number><foreign-keys><key app="EN" db-id="erv2s2vsnwtr24eswtrpv5xs5dsx29vpsxsp" timestamp="1527905021">1</key></foreign-keys><ref-type name="Web Page">12</ref-type><contributors><authors><author>International Diabetes Federation </author></authors></contributors><titles><title>International Diabetes Federation Atlas </title></titles><dates><year>2013</year></dates><urls><related-urls><url>www.idf.org/diabetesatlas.</url></related-urls></urls></record></Cite></EndNote>}

Several factors contribute to the high prevalence of diabetes in Kuwait, including the socioeconomic changes that followed the post-oil era, sedentary lifestyle, special food habits, increased life expectancy and increased risk factors for diabetes and obesity.{ ADDIN EN.CITE <EndNote><Cite><Author>Abdella</Author><Year>1998</Year><RecNum>4188</RecNum><DisplayText>[2]</DisplayText><record><rec-number>4188</rec-number><foreign-keys><key app="EN" db-

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Dyslipidemia and vascular changes that accompany diabetes accelerate the atherosclerosis process which is a major contributor to cardiovascular morbidity and mortality.{ ADDIN EN.CITE

<EndNote><Cite><Author>Jenkins</Author><Year>2004</Year><RecNum>5</RecNum><DisplayText>[3
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 resource-num>10.1002/dmrr.491</electronic-resource-num></record></Cite></EndNote>} In a sample
 of patients with diabetes in Kuwait, total cholesterol (TC) and low density lipoprotein cholesterol (LDL-C)
 levels were found to be above the accepted level as dictated by Kuwait Diabetes Guidelines, in 67% and
 86% of the patients respectively.{ ADDIN EN.CITE <EndNote><Cite><Author>Al-
 Adsani</Author><Year>2004</Year><RecNum>6</RecNum><DisplayText>[4]</DisplayText><record><r

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There is a validated and strong association between abnormal lipid values particularly LDL-C and CVD risk.{ ADDIN EN.CITE { ADDIN EN.CITE.DATA }} LDL-C is the principal carrier of cholesterol and is directly associated with atherosclerosis and cardiovascular disease risk.{ ADDIN EN.CITE { ADDIN EN.CITE.DATA }} Reduction of LDL-C has been associated with decreasing CVD events.{ ADDIN EN.CITE { ADDIN EN.CITE.DATA }} A meta-analysis by Kearney et al. demonstrated that for each one mmol/L reduction of LDL-C, there was 21% proportional reduction in major cardiovascular outcomes.{ ADDIN EN.CITE

<EndNote><Cite><Author>Cholesterol Treatment Trialists</Author><Year>2008</Year><RecNum>24</RecNum><DisplayText>[11]</DisplayText><record><rec-number>24</rec-number><foreign-keys><key app="EN" db-id="erv2s2vsnwtr24eswtrpv5xs5dsx29vpsxsp" timestamp="1527906313">24</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Cholesterol Treatment Trialists, Collaborators</author><author>Kearney, P. M.</author><author>Blackwell, L.</author><author>Collins, R.</author><author>Keech, A.</author><author>Simes, J.</author><author>Peto, R.</author><author>Armitage, J.</author><author>Baigent, C.</author></authors></contributors><titles><title>Efficacy of cholesterol-lowering therapy in 18,686 people with diabetes in 14 randomised trials of statins: a meta-analysis</title><secondary-title>Lancet</secondary-title></titles><periodical><full-title>Lancet</full-title></periodical><pages>117-25</pages><volume>371</volume><number>9607</number><keywords><keyword>*Cardiovascular Diseases/etiology/mortality/prevention & control</keyword><keyword>Cholesterol, LDL/blood</keyword><keyword>Diabetes Mellitus, Type 1/blood/complications/*drug therapy</keyword><keyword>Diabetes Mellitus, Type 2/blood/complications/*drug therapy</keyword><keyword>Female</keyword><keyword>Humans</keyword><keyword>Hydroxymethylglutaryl-CoA Reductase Inhibitors/*therapeutic

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 reducing major coronary events in patients with diabetes in many clinical trials.{ ADDIN EN.CITE { ADDIN
 EN.CITE.DATA }} However, some studies have highlighted the issue of under-treatment of dyslipidemia
 in patients with type 2 diabetes.{ ADDIN EN.CITE
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A number of studies have evaluated this relationship in patients admitted to hospitals in Kuwait. Saad et al. reported that the diagnosis of diabetes and elevated TC were evident in 41% and 56% of patients with acute myocardial infarction (MI) admitted to hospital in Kuwait.{ ADDIN EN.CITE { ADDIN EN.CITE.DATA }} Patients with diabetes who were admitted to hospital after acute MI had double the risk of in-hospital mortality when compared to patients without diabetes.{ ADDIN EN.CITE <EndNote><Cite><Author>Thalib</Author><Year>2004</Year><RecNum>18</RecNum><DisplayText>[16]</DisplayText><record><rec-number>18</rec-number><foreign-keys><key app="EN" db-id="erv2s2vsnwtr24eswtrpv5xs5dsx29vpsxsp" timestamp="1527905986">18</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Thalib, L.</author><author>Zubaid, M.</author><author>Suresh, C. G.</author><author>Rashed, W.</author><author>Shukkur, M.</author></authors></contributors><auth-address>Department of Community Medicine and Behavioural Sciences, Faculty of Medicine, Kuwait University, PO Box 24923, Safat, Kuwait. lthalib@hsc.kuniv.edu.kw</auth-address><titles><title>Diabetes mellitus as a contributor to the in-hospital mortality after acute myocardial infarction in Kuwait</title><secondary-title>Acta Cardiol</secondary-title></titles><periodical><full-title>Acta Cardiol</full-title></periodical><pages>317-22</pages><volume>59</volume><number>3</number><keywords><keyword>Acute Disease</keyword><keyword>Adult</keyword><keyword>Aged</keyword><keyword>Aged, 80 and over</keyword><keyword>Case-Control Studies</keyword><keyword>Coronary Care Units/*statistics & numerical data</keyword><keyword>*Diabetes Complications</keyword><keyword>Female</keyword><keyword>*Hospital Mortality</keyword><keyword>Hospitals, University/statistics & numerical

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There is very little data on the quality of diabetes management and quality improvement of diabetes care in Kuwait and other Arab states of the Gulf.{ ADDIN EN.CITE <EndNote><Cite><Author>Alhyas</Author><Year>2012</Year><RecNum>32</RecNum><DisplayText>[18]</DisplayText><record><rec-number>32</rec-number><foreign-keys><key app="EN" db-id="erv2s2vsnwtr24eswtrpv5xs5dsx29vpsxsp" timestamp="1527906889">32</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Alhyas, L.</author><author>McKay, A.</author><author>Majeed, A.</author></authors></contributors><auth-address>Department of Primary Care & Public Health, Imperial College London, London, United Kingdom. l.alhyas08@imperial.ac.uk</auth-address><titles><title>Prevalence of type 2 diabetes in the States of the co-operation council for the Arab States of the Gulf: a systematic review</title><secondary-title>PLoS One</secondary-title></titles><periodical><full-title>PLoS One</full-title></periodical><pages>e40948</pages><volume>7</volume><number>8</number><keywords><keyword>Adolescent</keyword><keyword>Adult</keyword><keyword>Aged</keyword><keyword>Arabs</keyword><keyword>Diabetes Mellitus, Type

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urls></urls></record></Cite></EndNote>} where most patients with diabetes are followed in the
primary healthcare (PHC) sector. Kuwait Diabetes Guidelines recommend using statin therapy to lower
LDL-C for the purpose of primary and secondary prevention of CVD events.{ ADDIN EN.CITE
<EndNote><Cite><Author>Health</Author><Year>2011</Year><RecNum>33</RecNum><DisplayText>[
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l%20Guideline%202014.pdf</url></related-urls></urls></record></Cite></EndNote>} The intermediate
outcomes, LDL-C and glycosylated hemoglobin (HbA1c), are frequently used to measure the quality of
care delivered to patients with diabetes.{ ADDIN EN.CITE
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Therefore, improving the care process indicators (proper management of dyslipidemia by using the evidence-based therapy such as statins), and intermediate outcomes (LDL-C) can improve the clinical outcomes of patients with diabetes treated at PHC in Kuwait.

This study explored the impact of implementing a protocol based intervention on reducing the CVD risk in patients with type 2 diabetes by improving management of LDL-C. As a secondary outcome, the audit measured the percentage of patients with type 2 diabetes who were on statin therapy, and the percentage of patients using statins who achieved the target goal of LDL-C (2.6 mmol/L).

Methods:

The governmental PHC sector of Kuwait consists of a number of polyclinics distributed over the different areas of the State of Kuwait to serve the healthcare needs of the population. This audit was conducted at Al-Naeem Diabetes Clinic, part of the primary healthcare polyclinic, Jahra health area, State of Kuwait.

Study Design

This study was a cross-sectional retrospective clinical audit focusing on LDL-C management in patients with type 2 diabetes.. The guidelines used in this study were Kuwait Clinical Practice Guidelines- Diabetes Mellitus, the Scottish Intercollegiate Guideline Network on management of diabetes (SIGN) and National Institute for Health and Care Excellence (NICE) clinical guideline 181. { ADDIN EN.CITE { ADDIN EN.CITE.DATA }} Primary prevention of CVD requires that people with diabetes apply healthy lifestyle changes and are offered to use statins at age 40. Kuwait guidelines recommends using <2.6mmol/L as target value for LDL-C and 1.8mmol/L if there is evident CVD.¹⁹ Statins such as simvastatin 40 mg, atorvastatin 10 mg and 20 mg were available and could be prescribed for the primary prevention of CVD at the time of this study. To complete the audit cycle, a basic audit was initially conducted; then a three-month intervention phase was implemented followed by a post-intervention audit. Data were retrospectively collected from the paper medical records from a computer generated random sample of record numbers for 100 patients with type 2 diabetes in both the basic and follow-up audits.

In the basic audit, the care process that we assessed was the management of LDL-C, using $\geq 2.6\text{mmol/l}$ as a cutoff level as a recommended target in Kuwait Diabetes Clinical Practice Guidelines.¹⁹

The intermediate outcome included the average LDL-C values, number of eligible patients on statin therapy and statin dose intensification. The basic audit identified deficiencies in the practices of management of high LDL-C when results were compared to guidelines standards. { ADDIN EN.CITE { ADDIN EN.CITE.DATA }}

Following the basic audit, an intervention phase was implemented which included applying a locally agreed protocol for lipid management based on lipid management recommendations in Kuwait Diabetes Clinical Practice Guidelines, NICE and SIGN recommendations on LDL-C management.{ ADDIN EN.CITE { ADDIN EN.CITE.DATA }}

All healthcare professionals working at Al Naeem Polyclinic received a copy of the protocol and an algorithm. Nurses and laboratory technicians were advised to highlight all laboratory results of LDL-C of 2.6 mmol/L or higher and forward it immediately to the corresponding treating physician. Following a presentation about audit, the healthcare team adopted the concept of audit as a practical way of improving the care process and the clinic reputation. Patients older than 40 years were informed by their 10 years CHD risk and were offered the choice to start statin therapy (simvastatin or atorvastatin) for the purpose of primary prevention. Subjects younger than 40 years with more than one risk factor were offered statin for primary prevention. For patients younger than 40 years with no risk factors but with LDL-C \geq 2.6mmol/L, statin therapy was considered by a joint decision taken with the patient. Lifestyle modifications, including weight management, increasing physical activity and smoking cessation were discussed with every patient with diabetes attending the clinic. Patients were also offered printed educational materials focussing on healthy food choices and encouraging physical activity. Following the 3-month intervention, a re-audit was conducted to assess the changes in the process of care (prescription of statins to eligible persons), and in the intermediate outcome (changes in LDL-C and TC values).

Sample selection

In each audit cycle, the audit team choose to randomly sample one hundred medical records of patients. Records were randomly selected from a computer generated list. Inclusion criteria were age between 40-80 years old, a diagnosis of type 2 diabetes for more than one year, LDL level >2.6mmol/L, and evidence of at least two visits to the clinic within one year of data collection. Patients who were using fibrates or any other lipid lowering agents were excluded from this study.

Data collection

A data collection sheet was used to record patients' clinical information. The variables assessed in each audit cycle included patient's demographics, biochemical laboratory results, diabetes duration, systolic and diastolic blood pressure, body mass index (BMI), smoking history, lipid modifying medications,

Statistical Analysis

The Statistical Package for Social Sciences (IBM SPSS Statistics version 22) was used for data analysis. The *independent samples t*-test was used for normally distributed data. The non-parametric test (Mann Whitney) was used to compare data of the basic audit and the re-audit when data were not normally distributed. Continuous variables were reported as the mean \pm SD and categorical variables were reported as percentages.

Ethical Approval

Ethical approval was received from Dasman Diabetes Institute (Institutional Review Board [IRB] number: RA 2013-21). The selected medical records were anonymised and identified by numbers only to ensure the confidentiality of study subjects.

Results:

Patient characteristics in basic and post-intervention audits

Table 1 shows the characteristics of the pre-audit and post-audit cohorts. A total of 200 medical records were examined. The mean age of patient's \pm SD was 52.4 ± 9 years in the basic audit and 52.5 ± 9.2 years in the re-audit. A total of 200 patients over the age 40 years (100 in the basic audit and 100 in the re-audit) were included, of whom 78 were females (41 in the basic audit and 37 in the re-audit). There were no significant statistical differences between the age, gender or nationality of patients, nor in diabetes duration, BMI and smoking between the pre- and post-intervention audits.

Statin therapy and dose titration

Out of 100 records examined in the baseline audit, only 26% of patients were on statin therapy. Most of those (20 cases) were on a low dose statin (simvastatin 20 mg). There was a significant increase in the number of patients receiving statin therapy in the post-intervention audit (85%) compared to 26% in baseline audit ($p < 0.001$). Dose intensification was also higher in the post-intervention audit than the baseline audit and the difference was significant ($p < 0.005$). Table 2 outlines the use of statin therapy; type of statin; dose; and titration of therapy.

Clinical and laboratory findings

Table 3 outlines the clinical and laboratory data of participants in basic and post-intervention audits. There was an improvement in the lipid profile in the post intervention audit. TC levels were significantly reduced from 5.15 ± 0.73 mmol/l to 4.68 ± 0.88 mmol/L and LDL-C from 3.37 ± 0.67 to 2.71 ± 0.79 mmol/L in the post-intervention audit ($p < 0.001$). Triglycerides levels (TG) were lower, and high density lipoprotein (HDL) levels were numerically higher in the post-intervention audit; however, these changes did not reach statistical significance. CV risk calculation showed a statistically non-significant reduction in the post intervention phase (from $18.46 \pm 11.1\%$ to $16.8 \pm 12.23\%$). There were no significant statistical differences between the levels of liver enzymes (ALT/AST), fasting blood glucose, serum creatinine and

number of insulin units between the pre- and post-intervention audits. Serum creatinine, fasting blood glucose and insulin units were slightly higher in the post intervention audit but the changes did not reach statistical significance.

Discussion:

This study aimed at improving the quality of care with regards to management of dyslipidemia in patients with diabetes followed at one primary care diabetes clinic in Kuwait. Clinical audits and feedback serve as quality improvement strategy that can minimize the gap between evidence-based recommendations and real-life actual practice. The audit cycle reported in this study focused on the care process indicator (prescription of statins to eligible persons with diabetes), and the intermediate outcomes of diabetes care (reduction of LDL-C levels and appropriate dose titration of statins) using a protocol-driven intervention.

The study identified deficiencies in lipid management in these patients (high level of average LDL-C and under-use of statin therapy). This was subsequently targeted by focused interventions which resulted in improved quality of care as evident in the results of the re-audit cycle. The interventions resulted in a significant, rapid, and marked improvement in key diabetes standards, including significant reduction of TC and LDL-C values, significant increase of statin prescriptions; and dose titration to match tolerance of eligible patients with type 2 diabetes.

The baseline audit cycle showed that many patients with type2 diabetes in the primary care sector have lipid values above treatment thresholds and management of dyslipidemia was suboptimal, leaving people at high cardiovascular risk. Diabetic dyslipidemia is under-treated in many countries.{

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The findings of this study shows that 74% patients with type 2 diabetes who are eligible to statin therapy did not receive a statin. In a study conducted by Braga et al. in Canada, 43% of patients with type 2

diabetes with high LDL-C (>2.6mmol/L) did not receive statin therapy.{ ADDIN EN.CITE { ADDIN EN.CITE.DATA }} Possible explanation for the under prescription of statins in this patient population is that patients with diabetes are on multiple medications and therefore, willingness to be prescribed another therapy is low .{ ADDIN EN.CITE

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Results of the baseline audit motivated the healthcare team to adopt a local protocol of lipid management and implement prescription of statins as a primary prevention strategy to patients with type 2 diabetes over the age of 40 years. There was also reduction in the TG and elevation of the HDL-C values, but these changes were not statistically significant. These findings were the direct effect of prescribing statin therapy to eligible people with type 2 diabetes (age > 40 years, LDL-C ≥ 2.6mmol/L and

with CHD risk ≥ 20 as measured by the UKPDS risk engine). Reduction of TC and LDL-C levels is a major parameter of quality improvement in the care of patients with type 2 diabetes.{ ADDIN EN.CITE <EndNote><Cite><Author>Agarwal</Author><Year>2012</Year><RecNum>43</RecNum><DisplayText>[26]</DisplayText><record><rec-number>43</rec-number><foreign-keys><key app="EN" db-id="erv2s2vsnwtr24eswtrpv5xs5dsx29vpsxsp" timestamp="1527973861">43</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Agarwal, G.</author><author>Kaczorowski, J.</author><author>Hanna, S.</author></authors></contributors><auth-address>Department of Family Medicine, McMaster University, 175 Longwood Road South, Hamilton, Ontario, Canada L8P 0A1.</auth-address><titles><title>Care for patients with type 2 diabetes in a random sample of community family practices in ontario, Canada</title><secondary-title>Int J Family Med</secondary-title></titles><periodical><full-title>Int J Family Med</full-title></periodical><pages>734202</pages><volume>2012</volume><dates><year>2012</year></dates><isbn>2090-2050 (Electronic)2090-2050 (Linking)</isbn><accession-num>22852083</accession-num><urls><related-urls><url><http://www.ncbi.nlm.nih.gov/pubmed/22852083></url></related-urls></urls><custom2>PMC3407621</custom2><electronic-resource-num>10.1155/2012/734202</electronic-resource-num></record></Cite></EndNote>}

The significant reduction of TC and LDL-C values obtained in the post intervention audit in this study replicates the findings reported in a 2-year audit of diabetes care in the UK.{ ADDIN EN.CITE <EndNote><Cite><Author>Oluwatowoju</Author><Year>2010</Year><RecNum>39</RecNum><DisplayText>[27]</DisplayText><record><rec-number>39</rec-number><foreign-keys><key app="EN" db-id="erv2s2vsnwtr24eswtrpv5xs5dsx29vpsxsp" timestamp="1527971824">39</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Oluwatowoju, I.</author><author>Abu, E.</author><author>Wild, S. H.</author><author>Byrne, C.

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In the Netherlands, improvements in the percentage of patients who met their target lipid levels were achieved following conducting a clinical audit.{ ADDIN EN.CITE <EndNote><Cite><Author>de Grauw</Author><Year>2002</Year><RecNum>41</RecNum><DisplayText>[29]</DisplayText><record>

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improvement in LDL values shortly after implementing an agreed upon lipid management protocol.

ADDIN EN.CITE { ADDIN EN.CITE.DATA } Results of a clinical audit on diabetes care in patients with type 2 diabetes in the United Arab Emirates showed improvement in LDL-C but that did not reach a significant level.

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The TRANSLATE trial used a multicomponent intervention to improve diabetes care in community primary

care practices which resulted in significant increase in the percentage of patients with type 2 diabetes achieving recommended LDL-C values after one year.{ ADDIN EN.CITE

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The intervention implemented in the study also resulted in a significant improvement in lipid management strategy by increasing the number of patients receiving statins from 26 % in the basic audit to 85% in the post-intervention audit. Another positive effect was noticed with regards to the dose intensification to the effective therapeutic dose (simvastatin 40 mg and atorvastatin 20 mg). Dose intensification is one of the methods used to achieve LDL-C lowering to recommended targets.{ ADDIN EN.CITE

<EndNote><Cite><Author>Bays</Author><Year>2014</Year><RecNum>44</RecNum><DisplayText>[33</DisplayText><record><rec-number>44</rec-number><foreign-keys><key app="EN" db-id="erv2s2vsnwtr24eswtrpv5xs5dsx29vpsxsp" timestamp="1527974192">44</key></foreign-keys><ref-type name="Journal Article">17</ref-type><contributors><authors><author>Bays, H. E.</author></authors></contributors><auth-address>Louisville Metabolic and Atherosclerosis Research Center, Louisville, KY, USA.</auth-address><titles><title>Lowering low-density lipoprotein cholesterol levels in patients with type 2 diabetes mellitus</title><secondary-title>Int J Gen Med</secondary-title></titles><periodical><full-title>Int J Gen Med</full-title></periodical><pages>355-64</pages><volume>7</volume><keywords><keyword>colesevelam</keyword><keyword>dyslipidemia</keyword><keyword>statin</keyword></keywords><dates><year>2014</year></dates><isbn>1178-7074 (Print)1178-7074 (Linking)</isbn><accession-num>25045281</accession-num><urls><related-urls><url>http://www.ncbi.nlm.nih.gov/pubmed/25045281</url></related-urls></urls><custom2>PMC4094576</custom2><electronic-resource-num>10.2147/IJGM.S65148</electronic-resource-num></record></Cite></EndNote>}

These results can be attributed to the effect of the intervention and feedback of the audit cycle that focused on LDL-C as the primary lipid target in primary prevention of CVD in patients with diabetes. The lower rate of statin

prescription, the low doses used, and the high baseline LDL-C in the baseline audit could have contributed to the significant improvement noticed in the re-audit.

It is hoped that the reduction of TC and LDL-C values would lead to a reduction in longer-term micro- and macro-vascular complications of diabetes. In this study, it is evident that obesity represents a risk factor among patients with diabetes. The high average BMI (30.5 Kg/m²) reported is consistent with findings of other studies conducted in Kuwait.{ ADDIN EN.CITE { ADDIN EN.CITE.DATA }} Initiating statin therapy in eligible patients did not seem to result in significant statistical differences in the laboratory values of fasting blood glucose, liver enzymes (ALT/AST), serum creatinine and number of insulin units between the pre- and post-intervention audits. This could be attributed to the fact that the patients received statin therapy only for a short time duration (three months or less).

A key issue in any quality improvement project is maintaining enthusiasm of the primary care team in the setting of a busy clinic to continue to adhere to the protocol. A plan to re-audit this practice in the near future to determine if the improvement achieved has been maintained and to further investigate management of other cardiovascular risk factors, blood pressure, blood glucose control, and smoking in addition to lipid management. Also the spectrum will include the impact of patient education, lifestyle changes, improving patient concordance with prescribed therapy as an example of patient centered intervention tools to normalize lipid values and reduce CVD risk. Future consideration of incentivizing good practice may be required as demonstrated by the implementation of Quality Outcomes Framework (QOF) in the UK where deaths from any cause and those related to specific conditions included in QOF – such as diabetes, hypertension and heart failure – declined over the period three to eight years after QOF was introduced.{ ADDIN EN.CITE { ADDIN EN.CITE.DATA }}

Study limitations and difficulties

This study had a number of limitations. The first hundred patients were not followed up in the re-audit. This was due to the unpredictable nature of clinic attendances of this population which largely consisted of migrant workers. However, both cohorts were comparable and further provides some assurance of this audit model for audits in this setting. Electronic medical records were still in the early stage of implementation at the clinic at the time of the study. Electronic records would make it easier to study a larger sample more easily. Being conducted over a short period of time, and on a relatively limited number of patients, it was difficult to assess the effect of statins on glucose homeostasis or to evaluate the possible side effects of statins on these patients. Medications that may influence lipid profile (e.g. thiazolidinediones [TZDs], Glucagon-like peptide-1 receptor agonists [GLP-1 RA], and the sodium/glucose cotransporter 2 [SGLT2] inhibitors) were not available the time when the study was conducted.

Conclusions

Dyslipidemia is directly related to cardiovascular morbidity and mortality in patients with type 2 diabetes, yet it seems to be under-treated in many countries. A clinical audit was effective in improving management of LDL-C in patients with type 2 diabetes attending a primary healthcare diabetes clinic in Kuwait. The basic audit revealed under-treatment of dyslipidemia which was evident as high LDL-C levels, low rate of statins prescription in patients eligible for statin therapy, and improper doses of statins. The implementation of a three-month intervention including a lipid management protocol resulted in significant reduction in TC and LDL-C values, significant increase in the number of patients prescribed statin therapy and in dose intensification. Clinical audit coupled with planned interventions can serve as effective and practical tool to improve management of cardiovascular risk factors in patients with type 2 diabetes in primary care practice but changes in clinical practice need to be maintained.

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A Clinical Audit to Assess Management of Low Density Lipoprotein Cholesterol at a Primary Care Diabetes Clinic in Kuwait

Table (1): Characteristics of participants in the audit cycle (n=200)

Variable		Pre intervention (n=100) (mean ± SD) No (%)	Post intervention (n=100) (mean ± SD) No (%)	P-value*
Age (year)		52.43±8.986	52.45±9.199	0.988,838
Gender	Female	41 (41.0)	37 (37.0)	0.562
	Male	59 (59.0)	63 (63.0)	
Ethnicity	Kuwaiti	17 (17.0)	18 (18.0)	0.847
	NK	55 (55.0)	51 (51.0)	
	Asian	28 (28.0)	31 (31.0)	
Diabetes Duration (year)		7.04±5.03	7.07±5.39	0.920
BMI (kg/m ²)		30.65±6.39	30.35±5.73	0.553
S m o k i n g	Y e s	1 3 (1 3 . 0)	1 2 (1 2 . 0)	0 . . 8 4 0
	N o	8 5 (8 5 . 0)	8 8 (8 8 . 0)	
	E x	2 (2 . 0)	0 (0 . 0)	

*P value is significant if <0.05. NK: non-Kuwaiti BMI: body mass index. Ex: former smoker.

Table 2: The use of statin therapy; type of statin; dose; and titration of therapy

	Pre intervention N=100 <i>Number (%)</i>	Post intervention N=100 <i>Number (%)</i>	Total N=200 <i>Number (%)</i>	P-value*
Statin therapy				
Yes	26 (26.0)	85 (85.0)	111 (55.5)	<0.001
No	74 (74.0)	15 (15.0)	89 (44.5)	
Statin type				
Simva 20	20 (20.0)	35 (35.0)	55 (27.5)	<0.001**
Simva 40	0 (0.0)	40 (40.0)	40 (20.0)	
Atorva 10	4 (4.0)	6 (6.0)	10 (5.0)	
Atorva 20	2 (2.0)	4 (4.0)	6 (3.0)	
No statin	74 (83.1)	15 (16..9)	89 (44.5)	
Dose titration				
Yes	2 (2.0)	42 (42.0)	44(22.0)	<0.001**
No	24 (24.0)	43 (43.0)	67(33.5)	
Not on statin	74 (74.0)	15 (15.0)	89 (44.5)	

*P value is significant if <0.05. Simva: Simvastatin; Atorva: Atorvastatin.

**P value true for all comparisons of each dose of each agent

Table 3: Clinical and laboratory data of participants in basic and post-intervention audit

Variable	Pre intervention Mean \pm SD	Post intervention Mean \pm SD	P-value*
Systolic BP (mmHg)	133.74 \pm 15.55	130.81 \pm 17.47	0.275
Diastolic BP (mmHg)	83.59 \pm 8.11	80.69 \pm 9.30	<0.044
HbA1c (%)	9.09 \pm 2.14	9.25 \pm 1.81	0.308 392
TC (mmol/L)	5.15 \pm 0.73	4.68 \pm 0.88	<0.001
TG (mmol/L)	1.98 \pm 0.96	1.81 \pm 0.85	0.490 134
LDL (mmol/L)	3.37 \pm 0.67	2.71 \pm 0.79	<0.001
HDL (mmol/L)	1.07 \pm 0.24	1.13 \pm 0.29	0.448 155
ALT (U/L)	24.47 \pm 14.51	20.88 \pm 9.76	0.172
AST (U/L)	21.50 \pm 9.44	18.77 \pm 5.54	0.192
Creatinin (μ mol/L)	62.79 \pm 26.66	64.63 \pm 24.91	0.262
FBG (mmol/l)	10.46 \pm 4.61	11.05 \pm 4.49	0.215
Insulin (u/ml)	15.18 \pm 26.82	15.56 \pm 24.31	0.545

*P value is significant if <0.05. TG: Triglycerides; HbA1c: Glycosylated Hemoglobin; TC: Total Cholesterol; HDL: High Density Lipoprotein Cholesterol; and LDL: Low Density Lipoprotein Cholesterol; ALT: Alanine Aminotransferase; AST: Aspartate Aminotransferase, FBG; Fasting Plasma Glucose